MAR 31 2000

K000722

510(k) Summary of Safety and Effectiveness

February 25,2000

Submitter Information:

PAJUNK GmbH
AM Holzplatz 5-7
78187 Geisingen
Germany

Contact: Mr. Egon Haegle, Quality Assurance Manager

Telephone: (49) 7704 9291 0
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Device Name:

Trade Name: Unipolar needles with Standard and Sprotte-tip
Common Name: Anesthesia Conduction Needle
Classification Name: Anesthesia Conduction Needle, with and without needle introducer

Predicate Device:

The Unipolar needles, with nerve stimulus connector, manufactured by Pajunk, GmbH are substantially equivalent to their needles with Standard and Sprotte-tip cleared for market by the FDA under 510(k) numbers K911260, K911202, K911221, and K923003. The physical characteristics, metal, plastic components, manufacturing and assembly process, gauges, lengths and packaging are identical to the needles cleared for market under the referenced 510(k) submissions. The contract sterilizer and sterilizing process are also identical to the cleared needles. The difference is the addition of an insulated wire, connector and insulating coating on the shank of the needle. The nerve stimulus cable, connector and coating are substantially equivalent to the cable, connector and coating of the B Braun, Model Stimuplex A series needles marketed in the United States. Other than the connector, insulated cable and coating, the needles are identical to the Standard and Sprotte–tip needles.

Device Description:

The PAJUNK Unipolar needles are single use sterile and nonpyrogenic needles used to gain entry or puncture the tissue in order to gain entry and locally inject anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application. PAJUNK GmbH does not produce the nerve stimulator and therefore validating the safety and efficacy of nerve stimulators is beyond the scope of this submission.

Intended Use:

The PAJUNK needles are used to puncture the tissue in order to gain entry and locally inject anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application.

Technology Characteristics:

The physical characteristics, coating, connector, metal and plastics used to produce the PAJUNK Unipolar needles are identical to the predicate devices described earlier in this *510(k) Summary of Safety and Effectiveness.* The needles are supplied in sealed polypropylene containers or polypropylene and styrol paper envelopes that are sealed to assure sterility.

Summary of Performance Testing:

The PAJUNK Unipolar needles were designed to conform to the applicable sections of the following recognized consensus standards. The testing included verifying conformance to these standards.

Standard	Issue Date	Title
DIN 13090/ISO 594	08.1984	Luer fittings w/wo locking feature
DIN 13097 Part 1	01.1980	Medical injection cannula
DIN 13097 Part 3	11.1979	Medical cannula
DIN 17442/ISO 9626	10.1977	Steel for medical instruments
DIN EN 550	07.1993	Sterilization of med. Prod.; Validation & routine controls for sterilization with ETO
DIN EN 556	01.1995	Sterilization of medical products, requirements for medical products that are labeled "sterile"
DIN EN 724	12.1994	Guidance on the application of EN29001 and EN46001 for non-active medical products
PrEN 868-1	10.1996	Packaging materials for the sterilization of packaged goods. Part 1: general requirements for the validation of the packaging of sterilized end-packaged products
DIN EN 868-2	03.1993	Packaging materials for the sterilization of packaged goods. Part 2: sterilization packaging, requirements and tests.
DIN EN 980	08.1996	Graphic symbols for marking medical products
DIN EN 1441	08.1994	Risk analysis for medical products
DIN EN 1707	01.1997	6% Luer cone connections for injection cannula and particular medical equipment
DIN EN/ISO 9626	06.1995	Cannula tube of non-rusting steel (SS) for the manufacture of medical products
DIN en 30993-1	12.1994	Biological evaluation of medical products – instructions for selection of tests
DIN EN 46001	12.1993	Particular requirements for medical products
DIN 17440	09.1996	Stainless Steels

Conclusion:

The PAJUNK Unipolar needles are as safe and effective as the predicate devices when used according to the instructions in the directions for use supplied with the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2000

Mr. Burk A. Brandt
PAJUNK GmbH
c/o CE Consultancy, Inc.
5010 NW Crescent Vly Drive
Corvallis, OR 97330

Re: K000722
Unipolar Needles with Standard and Sprotte-tip
Regulatory Class: II (two)
Product Code: BSP
Dated: February 28, 2000
Received: March 3, 2000

Dear Mr. Brandt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K000722

Device Name: Unipolar Needles with Standard and Sprotte-tip

Indications for use:

The PAJUNK needles are used to puncture the tissue in order to gain entry and inject local anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application.

Warning:
The Pajunk GmbH needles are not intended for RF ablation or any other type of ablation procedure.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000722